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10/782,014	02/19/2004	Selena Chan	42P14581	4300

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EXAMINER
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SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

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01/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/782,014

Applicant(s)

CHAN ET AL.

Examiner

Carolyn L. Smith

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-4,6,8-16 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,8-16 and 18-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 01162007.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's amendments and remarks, filed 10/16/07, are acknowledged. Amended claims 1, 6, 8, 10, 18, 20, 21, and 24 and cancelled claims 5, 7, 17, and 25-29 are acknowledged.

Applicant's arguments, filed 10/16/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-4, 6, 8-16, and 18-24 are herein under examination.

#### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection. This rejection is necessitated by amendment.

Applicant fails to point to any written support in the originally filed disclosure. There does not appear to be adequate written description for "wherein there is at least one polymer subsample created for each type of monomer present in the polymer sample" (claim 1) or "wherein both labeled and unlabeled instances of the one monomer type are randomly incorporated in the polymer subsample" (claim 1). While the abstract states "partially labeling only one of the monomer types in each polymer subsample", this does not provide adequate written support for "wherein there is at least one polymer subsample created for each type of monomer present in the polymer sample" which differs in scope. While the detailed description recites "multiple labels are incorporated into each chain", this differs in scope from "wherein both labeled and unlabeled instances of the one monomer type are randomly incorporated in the polymer subsample". Because the introduction of "wherein there is at least one polymer subsample created for each type of monomer present in the polymer sample" (claim 1) and "wherein both labeled and unlabeled instances of the one monomer type are randomly incorporated in the polymer subsample" (claim 1) do not appear to have adequate written support in the claims, specification, and/or drawings, as originally filed, these phrases are NEW MATTER. Claims 2-4, 6, and 8-12 are also rejected due to their dependency from claim 1.

***Claim Rejections - 35 USC § 112, First paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-16 and 18-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection. This rejection is maintained.

A method of use of monomers which are partially labeled such that the average time (of cleavage/detection?) between two labeled monomers is “significantly different” from the average time (of cleavage/detection?) of two unlabeled monomers, wherein the unlabeled monomers are the same type as the labeled monomers, is not enabled as neither the instant specification nor the prior art teach how to make and use monomers with such properties.

It is unclear what limitation is intended, as set forth below; however, the examiner has attempted to interpret the claims in light of the teachings of the specification, as follows. The instant specification teaches several methods of labeling monomers, including cross-linking (pages 14-15) to nanoparticles or antibodies, and polymerization/incorporation of labeled nucleotide “precursors” (page 11). The specification further teaches on page 11 that use of a “lower percentage” of labeled nucleotide precursors results in “signal stretching.” However, it is commonly known in the art that adjacent nucleotides in a polynucleotide chain have a fairly uniform spacing (or distance) regulated by the structure of the bonds between nucleotides. Adding labels to a previously formed polynucleotide would not affect the bond distance between two nucleotides in the chain. In a polymerization reaction, use of a “precursor” which affects the bond distance would be expected to result in a precursor which does NOT become incorporated, as the bond would not form, or would be expected to terminate polymerization, again, due to

irregular bond formation, and thus would result in a polymer wherein no two adjacent nucleotides are labeled. The prior art is silent with regard to how to make a partially labeled monomer or polymer wherein the time of cleavage/distance between adjacent monomers with labels is "significantly" different or longer than the time of cleavage/distance between similar adjacent monomers which are unlabeled.

As neither the instant specification nor the prior art teach how to make partially labeled monomers with the claimed properties, claims 13-16 and 18-24 are not enabled.

Applicant summarizes Figure 2 and Example 1. Applicant argues that claim 13 has been amended to remove the rejected language. This statement is found unpersuasive as claim 13 is still in its original form.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 13-16 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites "different monomer types comprising a polymer" in step (a). Those of skill in the art generally define a monomer as a single unit which can combine or polymerize with other monomers to FORM a polymer. By definition, a polymer is comprised of monomers.

As those skilled in the art do not usually consider a monomer as a unit which comprises polymers, it is unclear what is intended by a monomer types "comprising a polymer," therefore the claims are indefinite. If applicant intends monomer types "comprised within" the polymer or a similar limitation, then clarification through clearer claim language is requested. Claims 14-16 and 18-24 are also rejected due to their dependency from claim 13. This rejection is maintained.

Claim 13 limits a polymer to comprise monomer subtypes which are partially labeled such that an "average time between two adjacent labeled monomers is significantly larger than an average time between two adjacent monomers of the same type" which is generally confusing for the following reasons:

First, it is unclear what "average times" are intended; i.e. average time of separation (e.g. on a gel or through a column), average time of detection, average time of labeling, average time of decay of the labels attached to the monomers, etc.

Second, it is unclear what is intended by "two adjacent labeled monomers" versus "two adjacent monomers of the same type." The claims recite "only one of the monomer types ... is partially labeled", therefore all labeled monomers are of the "same type." As all labeled monomers are of the same type, then all "adjacent labeled monomers" are the same as "adjacent monomers of the same type," and the claim is both indefinite and not enabled. It is noted that any two adjacent monomers of the "same type" will be the same distance apart in a polymer regardless of labeling, therefore it is unclear how the distance between adjacent labeled monomers is to be different from the time between two adjacent UNLABELED monomers (of the same type as the labeled monomers). See the lack of enablement rejection above.

Third, it is unclear what is intended to be of the "same type." As indicated above, one interpretation is that the monomers are to be of the "same type." However, an alternate interpretation is that the LABELS are to be of the "same type" wherein the monomers may or may not be different.

As the limitation(s) intended by the phrases set forth above are unclear, claim 13 is indefinite. Claims 14-16 and 18-24 are also rejected due to their dependency from claim 13. This rejection is maintained.

The term "significantly larger" in claim 13 is a relative term which renders the claim indefinite. The term "significantly" with regard to "larger" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As one skilled in the art would not know how much larger an "average time" must be to be "significantly larger," the claim is indefinite. Claims 14-16 and 18-24 are also rejected due to their dependency from claim 13. This rejection is maintained.

Claim 13 recites the phrase "before labelling" in the last line of step (a). It is unclear what is intended to occur "before labeling," therefore the claim is indefinite. Claims 14-16 and 18-24 are also rejected due to their dependency from claim 13. This rejection is maintained.

Claims 6 and 18 recite the limitation "the labeled nucleic acid," each in lines 1-2. There is insufficient antecedent basis for this limitation in the claims, therefore the claims are indefinite. Parent claims 2 and 14 limit a polymer to be a nucleic acid, but do not recite a "labeled" nucleic acid. This rejection is maintained.



Applicant argues that claim 13 has been edited to remove rejected claim language. This statement is found unpersuasive as claim 13 is in its original form. The rejection to claims 6 and 18 is maintained as the amendments due not address the lack of antecedent basis as described above.

### *Conclusion*

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG

Application/Control Number:  
10/782,014  
Art Unit: 1631

Page 9

30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

December 31, 2007

/Carolyn Smith/  
Primary Examiner  
AU 1631